

REMARKS

Claims 1-121 are pending in the present application. Claims 14-84, 96, 107-109, 111-117 and 119-121 were previously withdrawn from consideration. In this response, claims 2-6, 8, 12, 13, 87, 91, 92, 94, 106, and 118 have been cancelled, claims 1, 7, 9, 11, 85, 86, 88-90, 93, 95, 97-101, and 110 have been amended, and new claims 122-145 have been added. Support for the amendments and new claims is found throughout the specification as originally filed. No new matter is added. Amendments not discussed below were made to correct claim dependencies or improve the form of the claim. Accordingly, claims 1, 7, 9, 10, 11, 85, 86, 88-90, 93, 95, 97-105, 110, and 122-145 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Information Disclosure Statements

Applicants thank the Office for reviewing and returning initialed copies of information disclosure statements submitted to date in this application. However, it was noted that U.S. 2006/022690 to Bley in the supplemental information disclosure statement filed on March 16, 2007 was not initialed as having been considered. Applicants have assumed that this reference was considered, but that the initialing here was inadvertently overlooked. If this understanding is incorrect, appropriate correction is requested.

Claim Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 88-90 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 88 has been amended to recite "a solvent system" in the third line of the claim. Accordingly, sufficient antecedent basis exists for the second recitation of solvent system in claim 88, and for the solvent system included in dependent claims 89 and 90.

In view of the above, withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claim Rejections Under 35 U.S.C. §102(b)

Claims 1-13, 86-95, 97-103, 106, and 118 stand rejected under 35 U.S.C. §102(b) as being allegedly being anticipated by O'Neill et al. (EP 0 347 000) ("O'Neill").

Applicants disagree that O'Neill is an anticipatory reference on the basis that it does not disclose each and every element of the rejected claims. The claims have been amended to recite a liquid formulation having the following features: 1) an amount of TRPV1 agonist between about 5% (w/v) to about 50% (w/v); 2) a penetration enhancer combination where a first penetration enhancer includes propylene glycol or diethylene glycol monoethyl ether, and a second penetration enhancer comprises ethyl oleate, oleic acid, or oleyl alcohol; and 3) pain relief for at least about two weeks after a single application. Support for these amendments is found at least in paragraphs [0076], [0086]-[0103], [0109], [0125], and [0171] of the specification as originally filed.

O'Neill fails to describe the TRPV1 concentration range, specific penetration enhancer combinations, and duration of pain relief required by the claims. For example, O'Neill teaches compositions that include lower amounts, i.e., from 0.001% to 5%, more preferably from 0.1% to 1% of a vanilloid compound (e.g., capsaicin). The specific penetration enhancer combinations and duration of pain relief is not mentioned at all. In view of the foregoing, O'Neill clearly fails to anticipate the rejected claims.

Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

Claim Rejections-35 U.S.C. §103(a)

Claims 1-13, 86-95, 97-106, and 110 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combined disclosures of O'Neill in view of Beerse et al. (U.S. 5,968,539) ("Beerse"). The Office states that O'Neill is silent with respect to a specific removal step in the treatment method but that it would have been obvious to one of ordinary skill to rinse the applied area to restore the skin to its original state as described by Beerse. Applicants have assumed

that the Office meant to apply the rejection to claims 104 and 105 since these are the only claims under consideration that include a removal composition. If this understanding is incorrect, appropriate correction is requested.

Applicants disagree that a case of obviousness has been established because the combination of O'Neill and Beerse fails to describe all elements of the rejected claims. The insufficiencies of O'Neill have been previously discussed. Beerse, which discloses an antimicrobial cleansing composition, fails to cure these defects.

At least in view of the above, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

Double Patenting

Claims 85-95, 97-103, and 118 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 16, 17, 20, 21, 24, 25, 28, 39-45, 47, 50-54, and 60-63, of co-pending Application No. 11/411,328. Applicants request that the issue of double patenting be deferred until an indication of allowable subject matter has been made in either application.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Office is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Office is invited to telephone the undersigned at the number given below.

In the event that the Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 524522001300. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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